REMARKS

In the non-Final Office Action mailed December 10, 2007, claims 1-31 were pending and stand rejected. Claims 1, 3, 4, 10-12, 20, 23, 24 and 27-31 are amended. Reconsideration of the present application as amended and withdrawal of the rejection of claims 1-31 is respectfully requested.

Claims 27-31 stand rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 6,193,721 to Michelson. Amended claim 27 recites "a holding element including a distal portion with a sharp distal tip positionable in a cannulation of the stabilization system, a proximal portion extending proximally from said distal portion, and an intermediate portion therebetween that projects outwardly from said proximal portion and said distal portion, said intermediate portion including at least one projection extending distally therefrom and outwardly from said distal portion adapted to engage an auxiliary element of the stabilization system and deliver a rotational force thereto, wherein said proximal portion of said holding element includes a shaft and a first instrument engaging portion projecting outwardly from said shaft that is adapted to receive a rotational force delivered to said holding element that rotates said proximal proximal portion and said distal portion in said cannulation and a second instrument engaging portion spaced from said first instrument engaging portion adapted to receive an axial force delivered to said holding element." Support for the amendments may be found, for example, in Figures 4-7 and 16-17 and paragraphs [0061]-[0064] and [0076]-[0078].

Pilot hole forming apparatus 60 (Fig. 31) of Michelson includes a central shaft 64 with a ring member 78 intermediate the distal shaft 66 and proximal portion of shaft 64. However, ring member 78 lacks at least one projection extending distally therefrom and outwardly from said distal portion adapted to engage an auxiliary element of the stabilization system and deliver a rotational force thereto. Furthermore, insertion tool 90 (Fig. 33) is a different instrument that cannot engage parts inside pilot hole forming apparatus 60. As shown in Fig. 34, insertion tool 90 engages a shaft 56 of compression post 54 having a collar 58. Collar 58 also lacks at least one projection extending distally therefrom and outwardly from the distal portion of shaft 56 adapted to engage an auxiliary element of the stabilization system and deliver a rotational force thereto.

In addition, neither housing 62 of apparatus 60 nor insertion tool 90 are operatively engaged to ring member 78 or central shaft 64 to provide a first instrument engaging portion projecting outwardly from shaft 64 adapted to receive a rotational force to the holding element that rotates the proximal portion and the distal portion of the holding element in the cannulation of the stabilization system. Also, neither housing 62 of apparatus 60 nor insertion tool 90 are operatively engaged to collar 58 of shaft 56 of compression post 54 to provide a first instrument engaging portion projecting outwardly from shaft 56 adapted to receive a rotational force to the holding element that rotates the proximal portion and the distal portion of the holding element in the cannulation of the stabilization system. Therefore, withdrawal of the rejection of claim 27 is respectfully requested.

Claims 28-31 depend from claim 27 and are allowable at least for the reasons claim 27 is allowable and for other reasons. For example, claim 30 recites the "intermediate portion includes a frusto-conical body that tapers from said distally oriented engagement surface to said first instrument engaging portion." Withdrawal of the rejection of claims 28-31 is respectfully requested.

Claims 1-16 and 18-26 stand rejected under 35 USC §103(a) as being unpatentable over Michelson in view of U.S. Patent No. 7,175,624 to Konieczynski et al.. Amended claim 1 recites, among other features, "a holding element including a distal portion and a proximal portion, said distal portion positionable through said cannulation with said distal portion extending distally from said distal opening of said auxiliary element configured to enter into bone to engage the spinal column to maintain a positioning of said stabilization device along the spinal column and said holding element releasably engages said auxiliary element in an interfitting relationship to prevent said auxiliary element from moving relative to said stabilization member, wherein when said holding element is engaged to said auxiliary element with said distal portion of said holding element extending distally from said auxiliary element and into bone of the spinal column, rotation of said proximal and distal portions of said holding element rotates said auxiliary element relative to said stabilization device." Support for the amendments may be found, for example, in the original claims and in Figures 4-7 and 16-17 and paragraphs [0061]-[0064] and [0076]-[0078].

The Office Action asserts that pilot hole forming apparatus 60 is a holding element that includes an intermediate portion 90/62. However, element 90 is an insertion tool of Fig. 33 while element 62 is a housing of pilot hole forming apparatus 60 of Figs. 31, 32. Insertion tool 90 and housing 62 were also considered to disclose a distally oriented engagement surface of the holding element, with pilot hole forming apparatus 60 having a first instrument engaging portion with central shaft 64 and sharp tip 65 adapted to receive a rotational force from a second portion spaced from the first portion where the second portion is impaction handle 68 of pilot hole forming apparatus 60. However, there is no teaching in Michelson of an operative engagement between pilot hole guide 60/insertion tool 90 and the auxiliary elements where either "releasably engages said auxiliary element in an interfitting relationship to prevent said auxiliary element from moving relative to said stabilization member" and that "with said distal portion of said holding element extending distally from said auxiliary element and into bone of the spinal column, rotation of said proximal and distal portions of said holding element rotates said auxiliary element relative to said stabilization device" as recited in amended claim 1.

Furthermore, Konieczynski et al. fail to teach the claimed interrelationship between the holding element and the auxiliary element missing from Michelson. In Konieczynski et al., tapered posts 104 are engaged to bone screws 140 applied to the vertebral bodies. Bone plate 120 includes resilient locking members 170, 170' that are positioned around tapered posts 104, and tapered posts 104 expand locking members 170, 170' as bone plate 120 is moved along posts 104 to bone screws 140 until locking members 170, 170' slide over the top of flanges 148 of bone screws 140 and snap into grooves 160 of bone screws 140. Posts 104 are then removed. See col. 11, lines 62 to col. 12, line 18. However, there is no disclosure that post 104 "releasably engages said auxiliary element in an interfitting relationship to prevent said auxiliary element from moving relative to said stabilization member" and that "with said distal portion of said holding element extending distally from said auxiliary element and engaged to the spinal column, rotation of said proximal and distal portions of said holding element rotates said auxiliary element relative to said stabilization device" as recited in amended claim 1. Therefore, since at least these features in claim 1 are not taught in the cited references, withdrawal of the rejection of claim 1 is respectfully requested.

Claims 2-19 depend from claim 1 and distinguish the cited references at least because claim 1 does and for other reasons. For example, amended claim 10 recites "wherein said holding element includes a distally oriented engagement surface for engaging said auxiliary element, said distally oriented engagement surface projecting outwardly around said distal portion of said holding element and including at least one projection for receipt in a recess in said auxiliary element in said interfitting relationship." Neither Michelson nor Konieczynski et al. teach these features. In Konieczynski et al., posts 104 are smooth and do not include a distal projection that is received in a recess of locking members 170, 170'. Michelson discloses a ring member 78 around central shaft 64, and housing 62 around central shaft 64 that projects from shaft 64 that is received in the plate hole (Fig. 32), but does not teach an operative relationship between ring member 78 or housing 62 with the auxiliary elements or that either includes a projection that is received in a recess of the auxiliary element in an interfitting relationship.

Amended claim 11 recites "wherein said holding element includes an intermediate portion between said distal portion and said proximal portion, said proximal portion including a shaft and a first driving tool engaging portion adjacent said intermediate portion that projects outwardly from said shaft, said intermediate portion further including a tapered body portion sloping from said distally oriented engagement surface to said first driving tool engaging portion." Neither Michelson nor Konieczynski et al. teach these features. Insertion tool 90 and housing 62 of pilot hole forming apparatus 60, identified in the office action as an intermediate portion, do not include a tapered body sloping from a distally oriented surface of pilot hole guide 60 or insertion tool 90. Furthermore, posts 104 in Konieczynski et al. do not taper between distally oriented engagement surface and a drive tool engaging portion that projects outwardly from a shaft of the proximal portion. Withdrawal of the rejection of claims 2-19 depending from claim 1 is respectfully requested.

Amended claim 20 recites, among other features, "a holding element including a distal portion positionable in said cannulation of said auxiliary element and configured to enter into bone of the spinal column, a proximal portion extending proximally from said distal portion, and an intermediate portion therebetween, wherein said intermediate portion includes a distally oriented engagement surface projecting outwardly from said distal portion that is adapted to interfit with said proximal engagement surface when said distal portion is positioned through said cannulation and

into bone of the spinal column to prevent said auxiliary element from moving relative to said stabilization device, said distal and intermediate portions of said holding element being movable when said distally oriented engagement surface is interfitted with said proximal engagement surface and said distal portion is entered into bone of the spinal column to move said auxiliary element in a desired position relative to said stabilization device." Support for the amendments may be found, for example, in the original claims and in Figures 4-7 and 16-17 and paragraphs [0061]-[0064] and [0076]-[0078].

As discussed above with respect to claim 1, neither Michelson nor Konieczynski et al. teach the claimed arrangement between the holding element and the auxiliary element. Michelson does not teach an operative engagement between pilot hole guide 60/insertion tool 90 and the auxiliary elements according to claim 20. Furthermore, Konieczynski et al. fail to teach the claimed interrelationship between the holding element and the auxiliary element since tapered posts 104 are engaged to bone screws 140 applied to the vertebral bodies and expand resilient locking members 170, 170' as bone plate 120 is moved along posts 104, but fail to disclose any distally oriented engagement surface on posts 104 that interfits with locking members 170, 170' to prevent locking elements 170, 170' from moving or to move locking members 170, 170' to a desired position relative to bone plate 120 when the distal portions of posts 104 are engaged to the spinal column. Therefore, since at least these features in claim 20 are not taught in the cited references, withdrawal of the rejection of claim 20 is respectfully requested.

Claims 21-26 depend from claim 20 and are allowable at least for the reasons claim 20 is allowable and for other reasons. For example, amended claim 23 recites "wherein said proximal portion of said holding element includes a first driving tool engaging portion proximally of and adjacent to said intermediate portion and a shaft extending proximally from said first driving tool engaging portion, said first driving tool engaging portion extending outwardly from said shaft, said intermediate portion further including a tapered body sloping from said distally oriented engagement surface to said first driving tool engaging portion, said proximal portion further including a second driving tool engaging portion on said shaft spaced from said first driving tool engaging portion and adjacent to a proximal end of said proximal portion." This combination of features is not taught in

the cited references, and withdrawal of the rejection of claims depending from claim 20 is respectfully requested.

Claim 17 stands rejected as being unpatentable under 35 USC §103(a) over Michelson in view of U.S. Patent Application Publication No. 2003/0083749 to Kuslich et al. Claim 17 depends from claim 1 and is allowable at least for the reasons claim 1 is allowable. Accordingly, withdrawal of the rejection of claim 17 is respectfully requested.

The present application including claims 1-31 is in condition for allowance, and a Notice of Allowance is respectfully requested. The Examiner is welcome to contact the undersigned to resolve any outstanding issues with respect to the present application.

Respectfully submitted,

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